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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/534,791	05/12/2005	Peter G Klimko	2444 US F	8680

7590 05/11/2007

Alcn Research
Attn Teresa J Schultz
6201 South Freeway
Q-148
Fort Worth, TX 76134-2099

EXAMINER	
RAMACHANDRAN, UMAMAHESWARI	
ART UNIT	PAPER NUMBER
1617	
MAIL DATE	DELIVERY MODE
05/11/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/534,791	KLIMKO ET AL.	
	Examiner	Art Unit	
	Umamaheswari Ramachandran	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 April 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The examiner notes the receipt of the amendments and remarks received in the office on 4/25/2007 amending claim 1. Claim 1 is pending.

The rejection of claim 1 under 35 U.S.C 102(a) is withdrawn due to the amendment of claim 1. The double patenting rejection of claim 1 is withdrawn due to the amendment of claim 1. The rejection of claim 1 under 35 U.S.C 103(a) is withdrawn due to the amendment of claim 1. Further examination and additional search necessitated the following rejections.

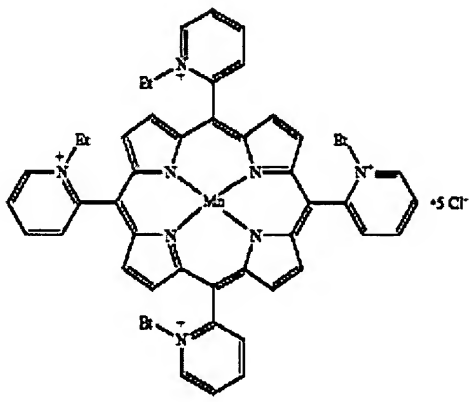
Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claim 1 is rejected under 35 U.S.C. 103(a) as being unpatentable over Fridovich et al. (US 2002/0042407) in view of Kato et al. (U.S. 5,665, 769).

Fridovich et al. teach a compound of formula (I) given below (para 0020). The reference further teaches that the mimetics compounds such as formula I are useful in the treatment of diabetes mellitus I or II (para 0020, 0035). The reference further teaches the mimetics compounds can also be used for the treatment of glaucoma, and macular degeneration in the eye (para 0031).



(Formula I)

The reference does not teach the compound in a method of treating diabetic retinopathy.

Kato teaches that among the retinal diseases resulting from systemic diseases, diabetic retinopathy is recognized as one of the diabetic microangiopathies, which are severe complications of diabetes (col. 1, lines 18-20). The reference also teaches macular degeneration, retinal edema and diabetic retinopathy as retinal disorders.

It would have been obvious to one of ordinary skill in the art at the time of the invention to use a compound of formula I in a method of treatment of diabetic retinopathy because of the teachings of Fridovich and Kato et al. Fridovich teach the compound of formula I to be useful in the treatment of diabetes and macular degeneration. Kato et al. teach that macular degeneration, retinal edema and diabetic retinopathy are retinal disorders and diabetic retinopathy as one of the diabetic microangiopathy, a severe complication of diabetes. Hence one of ordinary skill in the art would have been motivated to use the compound of formula I in the treatment of diabetic retinopathy as the compound has been taught to be useful in the treatment of

diabetes and another retinal disorder such as macular degeneration and one can expect similar therapeutic benefits or superior results in using the compound in the treatment of diabetic retinopathy.

Claim 1 is rejected under 35 U.S.C. 103(a) as being unpatentable over Fridovich et al. (WO 99/23097) in view of Kato et al. (U.S. 5,665, 769).

Fridovich et al. teach the compound of formula I (as above) (page 63, claim 16, formula I). The reference further teaches the compound to be useful in the treatment of edema, and type I and type II diabetes (page 16, lines 1-5).

The reference does not teach the compound in a method of treating diabetic retinopathy.

Kato et al.'s teachings discussed as above.

It would have been obvious to one of ordinary skill in the art at the time of the invention to use a compound of formula I in a method of treatment of diabetic retinopathy because of the teachings of Fridovich and Kato et al. Fridovich teach the compound of formula I to be useful in the treatment of diabetes and edema. Kato et al. teach that macular degeneration, retinal edema and diabetic retinopathy are retinal disorders and diabetic retinopathy as one of the diabetic microangiopathy, a severe complication of diabetes. Hence one of ordinary skill in the art would have been motivated to use the compound of formula I in the treatment of diabetic retinopathy as the compound has been taught to be useful in the treatment of diabetes and another retinal disorder such as retinal edema (a type of edema) and one can expect similar

therapeutic benefits or superior results in using the compound in the treatment of diabetic retinopathy.

Claim 1 is rejected under 35 U.S.C. 103(a) as being unpatentable over Piganelli et al. (U.S. 2003/0032634) in view of Kato et al. (U.S. 5,665, 769).

Piganelli et al. teach the compound of formula I (figure 9B) shown above. The reference further teaches the compound to be useful in the prevention, delay the onset of and/or limit the severity of diabetes (p 3, para 0027). The reference also teaches that low molecular weight antioxidants can be used to treat or prevent diabetes-specific microvascular disease of, for example, the retina, renal glomerulus and peripheral nerve (e.g., resulting in oedema, ischaemia and hypoxia-induced neovascularization in the retina (para 0027).

The reference does not teach the compound in a method of treating diabetic retinopathy.

Kato et al.'s teachings discussed as above.

It would have been obvious to one of ordinary skill in the art at the time of the invention to use a compound of formula I in a method of treatment of diabetic retinopathy because of the teachings of Piganelli et al. and Kato et al. Piganelli et al. teach the compound of formula I to be useful in the prevention, delay the onset of and/or limit the severity of diabetes and in the treatment or prevention of diabetes-specific microvascular disease of, for example, the retina. Kato et al. teach diabetic retinopathy as one of the diabetic microangiopathy, a severe complication of diabetes. Hence one of ordinary skill in the art would have been motivated to use the compound

of formula I in the treatment of diabetic retinopathy as the compound has been taught to be useful in the treatment or prevention of diabetes-specific microvascular disease of, for example, the retina, and one can expect similar therapeutic benefits or superior results in using the compound in the treatment of diabetic retinopathy.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Umamaheswari Ramachandran whose telephone number is 571-272-9926. The examiner can normally be reached on M-F 8:30 AM - 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

SREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER